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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/696,982	10/27/2000	F. Richard Bringhurst	0609.4430001/JAG/CMB	1728

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EXAMINER

ULM, JOHN D

ART UNIT PAPER NUMBER

1646

DATE MAILED: 07/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/696,982

Applicant(s)

Bringhurst et al.

Examiner

John Ulm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 5, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-23 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 16 6) ☐ Other:

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1) Claims 9 to 23 are pending in the instant application. Claims 2 and 6 to 8 have been canceled and claims 9 to 23 have been added as requested by Applicant in Paper Number 17, filed 05 May of 2003.

2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Claims 10, 13, 16, 19 and 22 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A properly dependant claim can not conceivably be infringed without infringing any of the claims from which it depends. The preamble in each of claims 10 and 22 indicates that they are drawn to alternative embodiments of the claims from which they depend. See M.P.E.P. 608.01(n)III.

5) Claims 9 to 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Catanzariti et al. publication (BioTechniques 15(3):474-479, Sep. 1993) in view of the combination of the Segre et al. patent (5,494,806) and the Bringham et al. publication (Endocrinology 132(5):2090-2098, May 1993) for those reasons of record as applied to claims 2 and 6 to 8 in section 6 of Paper Number 4. Applicant's arguments in traversal of this rejection essentially repeats those of record which have been answered on the record.

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The instant claims **encompass** a process of identifying agonist or antagonists of the human parathyroid hormone/parathyroid hormone related peptide receptor (PTHr) that was described in the Segre et al. patent by expressing that receptor in LLC-PK1 cells and measuring changes in the urokinase activity of those cells as an indicator of the activation or inhibition of that receptor by a test compound. As stated previously, the instant rejection is maintained because Bringham et al. described **LLC-PK1 cells** stably transfected rat and opossum PTHRs for the purpose of identifying agonists and antagonists thereto by measuring receptor-induced **production of cyclic AMP**, the Segre et al. patent described a **human** homolog of the rat and opossum **PTHRs** employed by Bringham et al. and expressly identified the LLC-PK1 cell line as one of five preferred cell lines for the recombinant expression of the human PTH/PTHrP receptor described therein, and because Catanzariti et al. described a method of "rapidly" identifying LLC-PK1-derived cell lines expressing heterologous receptors that couple to G_s-proteins by transfecting LLC-PK1 cells with DNA encoding a heterologous G protein-coupled receptor and screening for ligand-induced, **cyclic AMP-mediated** urokinase activity. The Bringham et al. and Segre et al. references provided ample motivation to express the **human PTHr** of Segre et al. in **LLC-PK1 cells** as described by Bringham et al. for the purpose of identifying agonists and antagonists thereto and Catanzariti et al. provide the motivation to measure the activation of that human receptor in that cell line by measuring ligand-induced, **cyclic AMP-mediated urokinase activity**. Because the instant specification shows that the PTHRs of Bringham et al. and Segre et al. were inherently coupled to both G_s and G_q proteins when expressed in LLC-PK1 cells, this

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combination of references taught all of the limitations of the instant claims either explicitly or inherently, and provided ample explicit motivation to combine those elements in the manner claimed.

Applicant has requested a legal basis for relying on inherency as a basis for an obviousness rejection. Applicant's attention is directed to M.P.E.P. 2112"

Requirements of Rejection Based on Inherency; Burden of Proof

The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103. "The inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness." *In re Napier*, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995) (affirmed a 35 U.S.C. 103 rejection based in part on inherent disclosure in one of the references). See also *In re Grasselli*, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983).

Applicant should also consider *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991), which held that "[p]rima facie case of obviousness of chemical composition is established if there is structural similarity between claimed and prior art subject matter, provided by combination of references or otherwise, and if prior art gives reason or motivation to make claimed composition". This decision further held that the "discovery that claimed composition possesses property not disclosed for prior art does not alone defeat prima facie case". This legal analysis is equally applicable to the method of the instant claims because the prior art provided specific motivation to practice a method that is fully encompassed by these claims and meets all of their limitations either explicitly or inherently.

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6) Applicant's arguments filed 05 May of 2003 have been fully considered but they are not persuasive for those reasons given above.

7) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM
PRIMARY EXAMINER
GROUP 1800